



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 507

[Docket No. FDA-2013-N-1043]

Draft Qualitative Risk Assessment of Risk of Activity/Animal Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm; Availability; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or we) is extending the comment period for a document we made available for public comment in the Federal Register of October 29, 2013 (78 FR 64428) (the draft RA). We are taking this action to make the comment period for the draft RA conform to the comment period for proposed rule entitled "Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals" (the proposed preventive controls rule for food for animals).

DATES: FDA is extending the comment period on the draft RA. Submit either electronic or written comments by March 31, 2014.

ADDRESSES: You may submit comments, identified by Docket No. FDA-2013-N-1043 by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

Mail/Hand delivery/Courier (for paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. FDA-2013-N-1043. All comments received may be posted without change to <http://www.regulations.gov>, including any personal information provided. For additional information on submitting comments, see the "Request for Comments" heading of the SUPPLEMENTARY INFORMATION.

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov>, and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kim Young, Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-2207.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of October 29, 2013, we published a notification with a 120-day comment period announcing the availability of, and requesting comment on, a document entitled "Draft Qualitative Risk Assessment of Risk of Activity/Animal Food Combinations for

Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm" (the draft RA). The purpose of the draft RA is to provide a science-based risk analysis of those activity/animal food combinations that would be considered low risk.

We conducted this draft RA to satisfy requirements of the FDA Food Safety Modernization Act (FSMA) to conduct a science-based risk analysis and to consider the results of that analysis in rulemaking that is required by FSMA.

In the Federal Register of October 29, 2013, we announced that we had used the results of the draft RA to propose to exempt certain animal food facilities (i.e., those that are small or very small businesses that are engaged only in specific types of on-farm manufacturing, processing, packing, or holding activities identified in the draft RA as low-risk activity/animal food combinations) from the proposed requirements of the Federal Food, Drug, and Cosmetic Act for hazard analysis and risk-based preventive controls (the proposed preventive controls rule). Interested persons were originally given until February 26, 2014, to comment on the proposed preventive controls rule.

FDA has received requests for an extension of the comment period on the proposed preventive controls rule for food for animals to allow interested persons an opportunity to consider the interrelationship between this proposed rule and the proposed rules entitled "Foreign Supplier Verification Programs for Importers of Food for Humans and Animals" (78 FR 45729, July 29, 2013) and "Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications" (78 FR 45782, July 29, 2013). We have considered the requests, and elsewhere in this issue of the Federal Register, we are granting an extension of the comment period to March 31, 2014, for the proposed preventive controls rule. We are extending

the comment period for the draft RA to March 31, 2014, to continue to make the comment period for the draft RA conform to the comment period for the proposed preventive controls rule.

II. Request for Comments

Interested persons may submit either electronic comments regarding the proposed rule to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

Dated: January 28, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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